

K112258

This 510k Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

# 1. Contact Details

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# 2. Device Name and Regulation

Trade Name of Device:

Neurotech Plus, Type 413

Regulation Number:

21 CFR 882.5890

Regulation Name

Transcutaneous electrical nerve stimulator for pain relief

Product Code:

GZJ, NYN, IPF

Device Class:

II

# 3. Identification of Equivalent Legally Marketed Device

510(k) Number:

K082011

Manufacturer:

Bio-Medical Research Ltd.

Trade Name:

MediStim XP, Type 281

510(k) Number: K082011

Manufacturer: Bio-Medical Research Ltd.

Trade Name: MediTens XP, Type 458

510(k) Number: K061516

Manufacturer: Compex Technologies

Trade Name: Staodyn® Max, Model 4470

510(k) Number: K971437

Manufacturer: Murray Electronics

Trade Name Bionicare Stimulator System Model Bio-1000

# 4. Description of Device

The Neurotech Plus is a portable, two-channel; battery operated system which can provide both Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS). The device is intended be available by prescription only. Included with the Neurotech Plus control unit, are a lead wire assembly, electrodes and instructions for use.

The Neurotech Plus contains ten program sets which have been each allocated an individual type number. Seven of these types offer a combination of NMES and TENS programs. There are two types which offer only NMES programs and one which has only TENS programs.

The lead-wire assembly contains the ID chip (EEPROM) that identifies the required program set. Each of the program set options are pre-programmed during manufacturing and no access to the configuration is available to either the end user or clinician. When each lead wire is connected to the unit and the outputs (A, B, C or D) to the electrodes, the two channels may be operated independently through the unit. Detailed diagrams for correct device usage and placement of the electrodes are available as part of the instructions for use.

### 5. Statement of Intended Use/Indications for Use

**Intended Use**: Dependent on the program chosen, the Neurotech Plus, Type 413 can deliver Neuromuscular Electrical Stimulation (NMES) for the activation of muscle for rehabilitation

and/or Transcutaneous Electrical Nerve Stimulation (TENS) for the activation of nerves for neuromodulation and management of pain.

### Indications for Use:

Models 431, 432, 433, 434, 436, 439, & 440 offer a combination of NMES or TENS programs.

### **NMES Indications for Use**

Maintain or increase the range of motion

Prevention or retardation of disuse atrophy

Re-educate muscles

Relax muscle spasms

Increase local blood circulation

Prevention of venous thrombosis of the calf muscles immediately after surgery

### **TENS Indications for Use**

Symptomatic relief and management of chronic, intractable pain

Relief of pain associated with arthritis

Adjunctive treatment in the management of post-surgical and post-trauma pain

Adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee (models 431, 432, 433 only)

# Models 437, 441 (NMES only indications for use)

Maintain or increase the range of motion

Prevention or retardation of disuse atrophy

Re-educate muscles

Relax muscle spasms

Increase local blood circulation

Prevention of venous thrombosis of the calf muscles immediately after surgery

### Model 438 (TENS only indications for use)

Symptomatic relief and management of chronic, intractable pain

Relief of pain associated with arthritis

Adjunctive treatment in the management of post-surgical and post-trauma pain

Sale of the device has been restricted to sale under a prescription order from a licensed practitioner.

# 6. Summary of Technological Characteristics

There are no new technological characteristics that could affect safety or effectiveness of the Neurotech Plus device. No new clinical tests have been submitted as part of this premarket notification.

The Neurotech Plus device complies with the following international standards:

- IEC 60601-1 (1998) + A1 (1991) + A2 (1995) Medical Electrical Equipment Part 1: General Requirements for Safety.
- IEC 60601-2-10 (1987) + A1 (2001) Medical electrical equipment Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.
- IEC 60601-1-2:2001 Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and Tests
- I.S. EN ISO 14971 2007

### 6.1 Program Sets

Tables 6.1.1 to 6.1.10 show the program parameters for each model of the Neurotech Plus.

Treatment Time (minutes)		Open	Open	Open	30	30	30	30	20	06	01	06	20	8
Additional Functions		Burst Toggle – 4 Hz. 250 usec Activation and output remains constant after pressing the burst button. Press Burst again to cancel. No ramp up/down will be implemented	Criss-cross Function, Burst - Ch1 125 Hz, 200 usec & Ch2 125 Hz, 200 usec. Activation and output remains constant for 10 minutes after burst button pressed. No ramp up/down will be implemented (See note 2)	Burst – 125 Hz, 175 usec. Activation and output remains constant while pressing burst button. No ramp up/down will be implemented	Тпgger	Trigger	Trigger	Trigger	Trigger					
Ramp Down (sec.)					5.0	0.5	0.5	6.5	5.0		0.5		0.5	
Ramp Up (sec.)					1.0	0.1	1.0	1.0	1.0		0.1		0.1	
Relax (sec.)					15	10	5	10	5		15		15	
Cont (sec.)					5	S	5	5	5		2		S	
Pulse Width (usec)	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time (see Note 1)	200.	200	250	300	300	300	300	300	100	200	100	200	100
Rate (Hz or pps)	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time (see Note 1)	66	Ch 2: 125	4	20	20	50	35	8	100	70	100	70	100
Intensity	Adj	Adj	Adj	Adj	Adj	Adj	Adj	Adj	Adj	Adj				
Screen Text	l d	P2 `	P3	P4	P5	P6	L J	P8	P9	P10				
Table 6.1+.1 Model 431	_	2	3	4	5	9	7	8	6	0				

Treatment Time (minutes)	Open	Open	Ореп	Open	30	30	30	20	20	20	10	70	20	70
Additional Functions		Burst -4Hz, 250 usec. Activation and output remains constant while pressing burst button. No ramp up/down will be implemented	Criss-cross Function, Burst - Ch1 125 Hz, 200 usec & Ch2 125 Hz, 200 usec. Activation and output remains constant for 10 minutes after burst button pressed. No ramp up/down will be implemented. (See note 2)	Burst -125Hz, 175 usec. Activation and output remains constant while pressing burst button. No ramp up/down will be implemented	Trigger	Trigger	Trigger	Trigger	Trigger					
Ramp Down (Sec.)					0.5	0.5	0.5	0.5	ĸ		0.5		0.5	
Ramp Up (Sec.)					1.0	1.0	1.0	1.0	1.0		1.0		1.0	
Relaxation (sec.)					15	10	5	10	S		15		15	
Contract (sec.)					5	5	5	ß	S		S		2	
Pulse Width (usec)	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3	200	200	250	300	300	300	300	300	100	200	100	200	100
Rate (Hz or pps)	modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle fine	66	Ch 2: 125	4	50	50	50	35	œ	100	70	100	70	100
Intensity	Adj	Adj	Adj	Adj	Adj	Adj	Adj	Adj	Adj	Adj				
Screen Text	Ы	72	<b>8</b> 3	P4	P5	P6	М	P8	P3	P10				
Table 6.1.2 Model 432	-	2	၈	7	5	9	7	æ	6	10				

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Treatment Time (minutes)	Open	Open	Open	30	30	30	. 30	20	70	20
Additional Functions		Burst – Frequency of 4 Hz, pulse width of 250 uscc. Activation and output remains constant while pressing burst button. Will ramp down over 3 sec. and up over 3 sec.	Burst – Frequency of 125 Hz, pulse width of 175 usec. Activation and output remains constant while pressing burst button. No ramp upodwn will be implemented.	Trigger	Trigger	Trigger	Trigger	Trigger		
Ramp Down (Sec.)			·	0.5	0.5	0.5	0.5	0.5		0.5
Ramp Up (Sec.)				1.0	1.0	1.0	1.0	1.0		0.1
Relaxation (sec.)				15	10	5	10	5		15
Contraction (sec.)				5	5	5	5	5		5
Width (usec)	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time		250	300	300	300	300	300	8	200
Rate (Hz or pps)	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	125	4	20	50	50	35	8	190	20
Intensity	Adjustable	Adjustable	Adjustable	Adjustable	Adjustable	Adjustable	Adjustable	Adjustable	Adjustable	Adjustable
Screen Text	Iq	P2	P3	75	P5	P6	P7	P8	&	P10
Table 6.1.3 Model 433	-	2	3	4	5	9	7	8	6	10

Table 6.1.4	Screen	Intensity	Rate	Width	Contraction	Relaxation	Ramp	Ramp	Additional	Treatment	
Model 434	Text		(Hz or pps)	(nsec)	(sec.)	(sec.)	Up	Down	Functions	Time	
							(Sec.)	(Sec.)		(minutes)	
	Ы	Adjustable	08	120	Continuous		2			Open	
					Stimulation		•			'	
	P2	Adjustable	2	180	Continuous		2			Open	
					Stimulation					'	
	P3	Adjustable	08	70 – 120	Continuous		2			Open	
					Stimulation		•				
	P4	Adjustable	80/2	180	Continuous		2			Open	
					Stimulation					•	
	PS	Adjustable	9/2	300	Continuous		2			20	
					Stimulation						
9	P6	Adjustable	<b>x</b>	300	5	5	0.1	0.5	Trigger	20	
	2	Adjustable	35	300	\$0	01	1.0	0.5	Trigger	30	
	æ	Adjustable	20	300	S	15	0.1	0.5	Trigger	33	
									•		
	ь	Adjustable	50	300	5	10	1.0	0.5	Trigger	30	
01	P10	Adjustable	20	300	5	5	1.0	0.5	Trigger	30	

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Treatment Time (minutes)	Open	Open	Open	30	30	30
Additional Functions	None	None	Burst – Frequency is 80hz, pulse width 300 usec with 8 pulses per burst; 2 bursts per second. 12 second cycle time – 2 seconds modulation from normal to burst, 8 seconds at burst, 2 seconds at burst, 2 from burst to normal. Frequency will increment during the transition to/from burst.	Trigger	Trigger	Trigger
Ramp Down (Sec.)	<b>V</b> N		∢ Z	1.5	1.5	1.5
Ramp Up (Sec.)	NA		<b>₹</b> Z	1.5	1.5	1.5
Relaxation (sec.)	NA		NA	25 (Remove Beep)	20 (Remove Beep)	5
Contraction (sec.)	<b>V</b>		<b>₹</b> Z	10	10	5
Width (usec)	150 to 250; modulates (increases) between 150 to 250 in 12 second cycle – remains at 150 for 3 seconds and 250 for 3 seconds of cycle time	50 to 100; modulates (increases) between 50 to 100 in 12 second cycle - remains at 50 for 3 seconds and 100 for 3 seconds of cycle time	150	300	300	300
Rate (Hz or pps)	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle - remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	125 to 4; modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 seconds and 4 for 3 seconds of cycle time	125	08	50	35
Intensity	Adjustable	Adjustable	Adjustable	Adjustable	Adjustable	Adjustable
Screen Text	P I	P2	2	P4	PS	P6
Table 6.1.5 Model 436	-	2	რ	4	5	9

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Relax time	5 seconds	5 seconds	5 seconds	5 seconds		Treatment Time	(minutes)	45				45					45	45	45	2	45		45		45				45			45		
Ramp Down Time	2 seconds	2 seconds	2 seconds	2 seconds		Pulse		AN				VV					NA	NA	AN		8 pulses per burst;	2 bursts per second	NA		NA				NA		•	YZ.		
Contract Time	3 seconds	3 seconds	3 seconds	3 seconds		Width	(nsec)	150 to 250;	modulates (increases) between	150 to 250 in 12 second cycle —	250 for 3 seconds of cycle time	50 to 100;	modulates (increases) between 50	to 100 in 12 second cycle -	remains at 50 for 3 seconds and	100 for 3 seconds of cycle time	175	250	175		175		175		250 to 150;	modulates (decreases) between	250 and 150 in 8 second cycle	(4/4)	50 to 100;	modulates (increases) between 50	to 100 in 6 second cycle (3/3)	150 to 250:	modulates (increases) between 150 and 250 in 10 second cycle	(6,6)
Ramp-Up time	2seconds	2seconds	2seconds	2seconds										s and 4 for 3		1								and 50 in 8		-	-							
Pulse Width	200□s	225 🗆 s	2500s	270 s		Rate	(Hz or pps)	125 to 4;	modulates (decreases) between 125 to 4 in 12 second	cycle – remains at 125 for 3 seconds and 4 for 3 seconds of englishment	פכרטוות אין כאבור וווונר	125 to 4;	modulates (decreases) between 125 to 4 in 12 second	cycle - remains at 125 for 3 seconds and 4 for 3	seconds of cycle time		125	4	Channel 1 - 4	Channel 2 - 125	08		125 to 50;	modulates (decreases) between 125 and 50 in 8 second cycle (4/4)	125				125 to 50;	modulates (decreases) between 125 to 50 in 6 second	cycle (3/3)	125 to 50:	modulates (decreases) between 125 and 50 in 10 second cycle (5/5)	
Frequency	2H09	55112	55Hz	50Hz					modulates (	cycle – n			modulates (	cycle – re	•								,	modulate						modulates (			modulate	
	s	s	8	s		Intensity		Adjustable				Adjustable					Adjustable	Adjustable	Adiustable		Adjustable		Adjustable		Adjustable				Adjustable			Adiustable		
Duration	20 minutes	25 minutes	30 minutes	40 minutes	:	Screen	Text	ы				P2					P3	P4	PS		P6		7		P8				<u> </u>			P10		
Table 6.1.6 Model 437	Program 1	Program2	Program 3	Program 4		Table 6.1.7	Model 438	1				2					3	4	5		9		7		8				6			01		
	_	_			L		_	_																										_

Treatment Time (minutes)	30	30	30	30	30	30	30	45	45	45
Additional Functions	Trigger	Burst –125 Hz, 175 usec. Activation and output remains constant while pressing burst button. Will ramp up over 3 sec. and down over 3 sec.	No-trigger	No-trigger						
Ramp Down (Sec.)	0.5	0.1	1.0	1.0	1.0	1.0	0.1			
Ramp Up (Sec.)	1.0	1.0	1.5	1.5	1.5	1:0	1.5			
Relaxation (sec.)	S	01	20	30	25	S	01			
Contraction (sec.)	ιΩ	01	01	10	8	S	10			
Width (usec)	300	300	300	300	250	300	250	250	175	150 to 250; modulates (increases) between 150 to 250 in 12 sec. cycle – remains at 150 for 3 sec. and 250 for 3 sec. of cycle time
Rate (Hz or pps)	90	20	50	20	35	.35	10	4	125	modulates (decreases) between 125 to 4 in 12 second cycle – remains at 125 for 3 sec. and 4 for 3 sec. of cycle time
Intensity	Adjustable	Adjustable	Adjustable							
Screen Text	Ы	P2	P3	P4	PS	P6	P7		£.	P10
Table 6.1.8 Model 439	-	2	3	4	5	9	7	∞	6	0

	Screen	Intensity	Rate	Width	Contraction	Relaxation	Ramp Up		Additional Functions	Treatment
Model 440	Text		(Hz or pps)	(nsec)	(sec.)	(sec.)	(Sec.)	Down (Sec.)		Time (minutes)
_	PI	Adjustable	125 to 4;	150 to 250;						Open
			modulates	modulates						
			(decreases)	(increases)						
			between 125 to 4	between 150 to						
			43	250 in 12 second						
				cycle - remains at						
				150 for 3 seconds						
			onds of	and 250 for 3						
			cycle time	seconds of cycle						
				time						
2	22	Adjustable	99 to 50;	150 to 250;						Open
			modulates	modulates			-			
			(decreases)	(increases)						
			between 99 and 50	between 150 to						
			in 8 second cycle	250 in 8 second						
			(4/4)	cycle (4/4)						
8	2	Adjustable	125	175					Criss-cross Function (See note 3)	Open
4	P4	Adjustable	4	250						
5	P5	Adjustable	95	300	5	01	1.0	0.5	Trigger	30
9	P6	Adjustable	50	300	10	01	1.0	0.5	Trigger	30
7	P7	Adjustable	50	300	10	20	1.0	0.5	Trigger	30
8	P8	Adjustable	20	300	10	0£	1.0	0.5	Trigger	30
6	P8	Adjustable	32	300		5	0.1	0.5	Trigger	20
01	P10	Adjustable	10	300	01	01	1.0	0.5	Trigger	20

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Table 6.1.10 Model 441	Screen Text	Intensity	Rate (Hz or pps)	Width (usec)	Contraction (sec.)	Relaxation (sec.)	Ramp Up (Sec.)	Ramp Down (Sec.)	Additional Functions	Treatment Time (minutes)
_	P1	Adjustable	50	300	5	10	0.1	0.5	Trigger	20
2	P2	Adjustable	50	300	01	10	1.0	0.5	Trigger	20
3	P3	Adjustable	50	300	01	20	0.1	0.5	Trigger	20
4	P4	Adjustable	50	300	01	30	1.0	0.5	Trigger	20
5	PS	Adjustable	35	300	5	2	0.1	0.5	Trigger	20
9	P6	Adjustable	4	300	Continuous Stimulation	mulation			No-Trigger	20
7	P7	Adjustable	10	300	20	2	1.5	0.5	Trigger	20
œ	P8	Adjustable	70	300	10	50	0.1	0.5	Trigger	20
6	P3	Adjustable	66	300	5	30	1.0	0.5	trigger	30

# 7. Substantial Equivalence Comparison Tables

Each model of the Neurotech Plus, Type 413 device has been compared to it's predicate device at the worst case program. Based on comparative analysis carried out between the proposed Neurotech Plus and the listed predicates, we believe that the proposed device is as safe, as effective and performs as well or better than the listed predicates.

Table 7.1		Neurotech Plus Model 431	Predicate Device Staodyn Max	Predicate Bionicare	Predicate MediTens
Mode or Program Name		Plan 3 (Highert Output)	Program E (Highest cuteur)	K971437	K082011
Mode of Flogram value		Fran 5 (mignest Output)	Frogram E (mgnest output)	Only has I mode	riogram 3
(For calculation of maxin	(For calculation of maximum rms current, and power				99Hz, 150µS
density)					
Waveform (e.g pulsed monophasic, biphasic)	tophasic, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, Monophasic	Pulsed, symmetric, biphasic
Shape (e.g. rectangular, spike, rectifred sinusoidal)	ike, rectified sinusoidal)	Rectangular, with interphase	Rectangular	Exponential, Spike	Rectangular, with interphase
		interval			interval
Maximum Output Voltage (volts)(+/- 10%)	(volts)(+/- 10%)	35.0V @ 500 Ω	30.0V @ 500 Ω	12V 500Ω	37.5V @ 500 Ω
	1	75.0V @ 2 kΩ	Not available	Not available	70.0V@ 2 kΩ
	1	70.3V @ 10 kΩ	Not available	Not available	71.8V @ 10 kΩ
Maximum Output Current (specify units)(+/- 10%)	(specify units)(+/- 10%)	70.0mA @ 500 Ω	60.0 mA @ 500 \triangle	24mA @ 500Ω	75.0mA @ 500 $\Omega$
		37.5mA @ 2 kΩ	Not available	Not available	35,0mA @ 500 Ω
		7.0mA @ 10 kΩ	Not available	Not available	7.0mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)	s)(+/- 10%)	7.8V @ 500 Ω	. 8.9V @ 500Ω	4.3V Estimated assuming a square	6.5V@500Ω
	-			pulse shape 0.64ms	
		16.8V @ 2 kΩ	Not available	Not available	14.2V@2kΩ
		7.9V @ 10 kΩ	Not available	Not available	4.95V@10kΩ
RMS Output Current (specify units)(+/- 10%)	ify units)(+/- 10%)	15.7mA @ 500 Ω	17.8mA @ 500 Ω	8.6mA	13mA@500Ω
		8.4mA @ 2 kΩ	Not available	Not available	7.1mA@2kΩ
		0.8mA @ 10 kΩ	Not available	Not available	0.5mA@10kΩ
Duration of primary (depolarizing) phase (usec)	larizing) phase (usec)	250uS	60-350uS	640 µS	150uS
Pulse Duration (usec)		400-600uS (uS both phases +	700uS (350 uS both phases)	640 µS	400μS
		100µS interphase delay)			Both phases
Frequency (Hz)[ or Rate (pps) ]	[ (sdt	4 to 125Hz	80 to 125 Hz	ZH 001	4 to 99 Hz
For multiphasic	Symmetrical phases?	Yes	Yes	N/A	Yes
waveforms only:	Phase duration (include	100 to 250µS	60-350uS	N/A	100 to 150uS

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Table 7.1	Neurotech Plus Model 431	Predicate Device Staodyn Max K06 i 516	Predicate Bionicare K971437	Predicate MediTens K082011
units) state range, if applicable)(both phases, if asymmetrical)				
Net Charge(microcoulombs (uC) per pulse) (if zero,	0 μC @ 500 Ω	0μC @ 500Ω	21 µC @ 500Ω	0 μC @ 500 Ω
state method of achieving zero net charge.)	Symmetric, biphasic and leading	Symmetric, biphasic and leading		Symmetric, biphasic and leading
	polarity alternates for each	polarity alternates for each		polarity alternates for each
	successive pulse.	successive pulse.		successive pulse.
Maximum Phase Charge (uC)	10.5 to 17.5 μC @ 500 Ω	9 to 21 μC @ 500 Ω	21 µC @ 500Ω	7,5 to 11.25 μC @ 500 Ω
Maximum Current Density (mA/cm2, r.m.s)	0.80mA/cm²(T=1sec)	Program E	0.08 mA/ cm <sup>2</sup>	0.672mA/cm <sup>2</sup>
{@ 500 Ω Where T is the duration of averaging for		Using 2" square electrode = 17 8 mA/25 cm <sup>2</sup>	i.e. 8.6mA/108 cm <sup>2</sup>	5cm round electrode)
worst case (highest) output}		$= 0.71 \mathrm{mA/cm^2}$	Using 12 x 9 cm electrodes	
Maximum Average Current (average absolute value).	3.5mA	5.3mA	2.1mA	. 2.25mA
mA {@ 500 Ω}				
Maximum Average Power Density, (W/ cm²), (using	6.2mW (T=1sec)	6.3 mW/cm²	0.34 mW/cm <sup>2</sup>	4.4mW/ cm²
smallest electrode conductive surface area) { @ 500 \textit{ Q} Where T is the output duration}	50mm round electrode	<u>Program E</u> Using 2" square electrode		50mm round electrode
Burst Mode (i.e., pulse (a) Pulses per burst	N/A	8	N/A	N/A
trains);	Burst mode is simply an alternate			Burst mode is simply an alternate
	frequency-pulse witdh			frequency-pulse witdh
	combination. There are actually			combination. There are actually
	no intermittent bursts			no intermittent bursts
(b) Bursts per second	N/A	2	N/A	N/A
(c) Burst duration	N/A	60:0	N/A	N/A
(seconds)				
(d) Duty Cycle [ Linc (b) x	N/A	.18	N/A	N/A
Line (c) 1				
ON Time (seconds)	N/A	N/A	N/A	N/A
OFF Time (seconds)	N/A	N/A	N/A	N/A
[m]				

Table 7.2		Neurotech Plus Model 432	Predicate Device Staodyn Max K061516	Predicate Bionicare K971437	Predicate MediTens K082011
Mode or Program Name		Plan 3	Program E (Highest output)	Only has 1 mode	Program 3 (99Hz, 150µS)
Waveform (e.g pulsed monophasic, biphasic)	ophasic, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, Monophasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)	ke, rectified sinusoidal)	Rectangular, with interphase interval	Rectangular	Exponential, Spike	Rectangular, with interphase
					interval
Maximum Output Voltage (volts)(+/- 10%)	(volts)(+/- 10%)	35.0V @ 500 Ω	30.0V @ 500 Ω	12V 500Ω	37.5V @ 500 Ω
		75.0V @ 2 KΩ	Not available	Not available	70.0V@ 2 kΩ
		70.3V @ 10 kΩ	Not available	Not available	71.8V @ 10 kΩ
Maximum Output Current (specify units)(+/- 10%)	(specify units)(+/- 10%)	70.0mA @ 500 Ω	60.0 mA @ 500 Ω	24mA @ 500Ω	75.0mA @ 500 Ω
		37.5mA @ 2 kΩ	Not available	Not available	35.0mA @ 500 Ω
		7.0mA @ 10 kΩ	Not available	Not available	7.0mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)	(%01 -/+)(s	7.8V @ 500 Ω	8.9V @ 500 Ω	4.3V	6.5V@500Ω
				Estimated assuming a square pulse	
				shape 0.64ms	
		16.8V @ 2 kΩ	Not available	Not available	14.2V@2kΩ
		7.9V @ 10 kΩ	Not available	Not available	4.95V@10kΩ
RMS Output Current (specify units)(+/- 10%)	ify units)(+/- 10%)	15.7mA @ 500 Ω	17.8mA @ 500 Ω	8.6mA	13mA@500Ω
		8.4mA @ 2 kΩ	Not available	Not available	7.1mA@2kΩ
		0.8mA @ 10 kΩ	Not available	Not available	0.5mA@10kΩ
Duration of primary (depolarizing) phase (usec)	arizing) phase (usec)	150-250uS	60-350uS	640μS	150uS
Pulse Duration (usec)		400-600uS (uS both phases + 100μS	700uS (350 uS both phases)	. 640 μS	400µS
		interphase delay)			Both phases
Frequency (Hz)[ or Rate (pps) ]	ps) ]	4-125Hz	80 to 125 Hz	ZH 001	4 to 99 Hz
For multiphasic	Symmetrical phases?	Yes	N/A	No	Yes
waveforms only:	Phase duration	60-350uS	N/A		100 to 150uS
	(include units) state				
	range, if				

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Table 7.2	Neurotech Plus Model 432	Predicate Device Staodyn Max K061516	Predicate Bionicare K971437	Predicate MediTens K082011
applicable)(both phases, if asymmetrical)				
Net Charge(microcoulombs (uC) per pulse) (if	0 μC @ 500 Ω	0μC @ 500 Ω	21 µC @ 500Ω	0 μC @ 500 Ω
zero, state method of achieving zero net charge.)	Symmetric, biphasic and leading	Symmetric, biphasic and leading		Symmetric, biphasic and leading
	polarity alternates for each successive	polarity alternates for each		polarity alternates for each
	pulse.	successive pulse.		successive pulse.
Maximum Phase Charge (uC)	14.0 μC @ 500 Ω	9 to 21 μC @ 500 Ω	21 μC @ 500Ω	7.5 to 11.25 µC @ 500 Ω
Maximum Current Density (mA/cm², r.m.s)	0.80mA/cm²(T=1sec)	Program E	0.08 mA/ cm²	0.672mA/cm²
(@ 500 Ω Where T is the output duration)		Using 2" square electrode =17.8 mA/25 cm <sup>2</sup> = 0.71mA/ cm <sup>2</sup>	i.e. 8.6mA/108 cm² Using 12 x 9 cm electrodes	5cm round electrode)
Maximum Average Current (average absolute	3.5mA	5.3mA	2.1mA	2.25mA
value), mA {@ 500 \( \overline{\alpha} \)				
Maximum Average Power Density, (W/ cm²),	6.2mW (T=1sec)	6.3 mW/cm²	0.34 mW/cm²	4.4mW/ cm²
(using smallest electrode conductive surface area)		<u>Program E</u> Using 2" square electrode		50mm round electrode
{@ 500 Ω Where T is the output duration}				
Burst Mode (i.e., pulse (a) Pulses per burst	Burst mode is simply an alternate	80	N/A	Burst mode is simply an alternate
trains):	frequency-pulse witch combination.			frequency-pulse witdh
	There are actually no intermittent			combination. There are actually
	bursts			no intermittent bursts
(b) Bursts per	N/A	2	N/A	NA
second				
(c) Burst duration	N/A	60'0	N/A	N/A
(seconds)				
(d) Duty Cycle	N/A	.18	N/A	N/A
Line (b) x Line (c)				
ON Time (seconds)	N/A	N/A	N/A	N/A
OFF Time (seconds)	N/A	N/A	N/A	NA
Additional Features (specify, if applicable)	N/A	N/A	N/A	N/A
		T		

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Model 433         Standyn MA         Standyn Ma         Standyn Ma         Standyn Ma         Kodel 516         Polan 2         Publed, symmetric.	Staodyn Max K061516 Program E (Highest output) Pulsed, symmetric, biphasic	Bionicare	MediTens
m Name  m Name  m Name  m Name  m Name  m Name  pulsed monophasic. biphasic)  pulsed monophasic. biphasic)  pulsed monophasic. biphasic)  rectangular, with interphase  interval  35.0V ⊕ 50θ.Ω  75.0V ⊕ 2 kΩ  70.3V ⊕ 10 kΩ  70.0m A ⊕ 10 kΩ  15.7V ⊕ 2 kΩ  75.9V ⊕ 10 kΩ  15.7V ⊕ 2 kΩ  75.9V ⊕ 10 kΩ	Program E (Highest output)  Pulsed, symmetric, biphasic	K971437	K082011
pulsed monophasic, biphusic)         Pulsed, symmetric, biphusic           ngular, spike, rectified sinusoidal)         Rectangular, with interphase interval           ut Voltage (volts)         35.0V @ 500 Ω           T5.0V @ 2 kΩ         70.3V @ 10 kΩ           T0.0mA @ 10 kΩ         7.0mA @ 10 kΩ           T.9V @ 10 kΩ         7.3V @ 500 Ω           T.9V @ 10 kΩ         7.9V @ 10 kΩ           mery (depolarizing) phase (usec)         15.7V @ 2 kΩ           T.8mA @ 2 kΩ         7.8mA @ 10 kΩ           T.8mb @ 10 kΩ         150.250uS           (usec)         150.250uS           I or Rate (pps) ]         400-600uS (uS both phases + 100 kB)           I or Rate (pps) ]         41.25Hz           Symmetrical phases?         Yes	Pulsed, symmetric, biphasic	Only has I mode	Program 3
pulsed monophasic, biphasic)         Pulsed, symmetric, biphasic           ngular, spike, rectified sinusoidal)         Rectangular, with interphase           nut Voltage (volts)         35.0V @ 500 Ω           nut Current (specify units)         70.0mA @ 500 Ω           nut Current (specify units)         70.0mA @ 10 kΩ           nut Current (specify units)         7.3V @ 500 Ω           nrent (specify units)(+/- 10%)         15.7V @ 2 kΩ           nrent (specify units)(+/- 10%)         14.6mA @ 500 Ω           nrent (specify units)(+/- 10%)         14.6mA @ 2 kΩ           nary (depolarizing) phase (usec)         150-250uS           (usec)         160-250uS           nary (depolarizing) phase (usec)         160µS interphase delay)           for Rate (pps)           4125Hz           Symmetrical phases?         Yes	Pulsed, symmetric, biphasic		99Hz, 150µS
ngular, spike, rectified sinusoidal)         Rectangular, with interphase interval           ut Voltage (volts)         35.0V @ 500 Ω           T5.0V @ 2 kΩ         70.3V @ 10 kΩ           70.0mA @ 10 kΩ         7.0mA @ 10 kΩ           7.3V @ 10 kΩ         7.3V @ 10 kΩ           15.7V @ 2 kΩ         7.9V @ 10 kΩ           16.5mA @ 500 Ω         7.8mA @ 2 kΩ           16.5mA @ 10 kΩ         7.8mA @ 2 kΩ           16.5mA @ 10 kΩ         7.8mA @ 10 kΩ           16.5mA @ 10 kΩ         7.8mA @ 10 kΩ           16.5mA @ 10 kΩ         7.8mA @ 10 kΩ           16.5mA @ 10 kΩ         150.250uS           160uS interphase deluy)         100uS interphase deluy)           16 r Rate (pps)         44125Hz           16 symmetrical phases?         Yes		Pulsed, Monophasic	Pulsed, symmetric, hiphasic
interval  ut Voltage (volts)  ut Current (specify units)  interval  35.0V @ 500 \( \text{interval} \)  70.3V @ 10 k\( \text{interval} \)  70.0mA @ 2 k	Rectangular	Exponential, Spike	Rectangular, with interphase
ut Voltage (volts)         35.0 V ⊕ 500 Ω           nt Current (specify units)         70.0mA ⊕ 10 kΩ           nt Current (specify units)         7.0mA ⊕ 10 kΩ           ntrent (specify units)(+/- 10%)         15.7 V ⊕ 2 kΩ           ntrent (specify units)(+/- 10%)         14.6mA ⊕ 500 Ω           ntrent (specify units)(+/- 10%)         14.6mA ⊕ 2 kΩ           ntrent (specify units)(+/- 10%)         14.6mA ⊕ 2 kΩ           ntrent (specify units)(+/- 10%)         16.8mA ⊕ 10 kΩ           ntrent (specify units) phase (usec)         150-250uS           ntrent (specify units) phase (usec)         160µS interphase delay)           lor Rate (pps)           4-125Hz                     Symmetrical phases?                     Yes			interval
75.0V @ 2 kΩ   70.3V @ 10 kΩ   70.3V @ 10 kΩ   70.3V @ 10 kΩ   70.3V @ 10 kΩ   70.0M & 10 kΩ   70.0M & 2 kΩ   7.3V @ 500 Ω   7.3V @ 2 kΩ   7.3V @ 10 kΩ	30.0V @ 500 Ω	12V 500Ω	37.5V @ 500 Ω
70.3V @ 10 kΩ	Not available	Not available,	70.0V@ 2 kΩ
ut Current (specify units)         70.0mA @ 500 Ω           37.5mA @ 2 kΩ           7.0mA @ 10 kΩ           7.3V @ 500 Ω           15.7V @ 2 kΩ           7.9V @ 10 kΩ           7.9V @ 10 kΩ           7.9V @ 10 kΩ           7.8mA @ 2 kΩ           7.8mA @ 2 kΩ           7.8mA @ 10 kΩ           6.8mA @ 10 kΩ           150-250uS           100µS interphase deluy)           [or Rate (pps)]           A+125Hz           Symmetrical phases?           Yes	Not available	Not available	71.8V @ 10 kΩ
37.5mA @ 2 kΩ	60.0 mA @ 500 Ω	24mA @ 500Ω	75.0mA @ 500 Ω
7.0mA @ 10 kΩ    7.3V @ 500 Ω    15.7V @ 2 kΩ    15.7V @ 10 kΩ    14.6mA @ 500 Ω    17.8mA @ 2 kΩ    17.8mA @ 2 kΩ    18.8mA @ 10 kΩ    19.8mA @ 10 kΩ	Not available	Not available	35.0mA @ 500 Ω
15.7V @ 500 Ω	Not available	Not available	7.0mA @ 10 kΩ
15.7V @ 2 kΩ  7.9V @ 10 kΩ  14.6mA @ 500 Ω  7.8mA @ 2 kΩ  7.8mA @ 2 kΩ  7.8mA @ 10 kΩ  150-250uS  150-250uS  100μS interphase delay)  1 or Rate (pps) ]  Symmetrical phases?  Symmetrical phases?  Yes	8.9V @ 500 Ω	4.3V	6.5V@500Ω
15.7V @ 2 kΩ  17.9V @ 10 kΩ  7.9V @ 10 kΩ  7.8mA @ 500 Ω  7.8mA @ 10 kΩ  7.8mA @ 10 kΩ  0.8mA @ 10 kΩ  150-250uS  (usec)  100µS interphase deluy)  1 or Rate (pps) ]  Symmetrical phases?  1 Symmetrical phases?	HSU	Estimated assuming a square pulse	
15.7V @ 2 kΩ  17.9V @ 10 kΩ  17.8mA @ 500 Ω  7.8mA @ 10 kΩ  7.8mA @ 10 kΩ  7.8mA @ 10 kΩ  7.8mA @ 10 kΩ  150-250uS  100μS interphase delay)  1 or Rate (pps) ]  Symmetrical phases? Yes		shape 0.64ms	
7.9V @ 10 kΩ   14.6mA @ 500 Ω   14.6mA @ 2 kΩ   15.8mA @ 10 kΩ   16.8mA	Not available	Not available	14.2V @2kΩ
14.6mA @ 500 Ω   14.6mA @ 500 Ω   7.8mA @ 2 kΩ   7.8mA @ 10 kΩ   150-250uS   150-250uS   100μS interphase delay   100μS interphase   100μS interphas	Not available	Not available	4.95V@10kΩ
7.8mA @ 2 kΩ  0.8mA @ 10 kΩ  0.8mA @ 10 kΩ  150-250uS  400-600uS (uS both phases + 100μS interphase delay)  or Rate (pps) ]	17.8mA @ 500 Ω	8.6mA	13mA@500Ω
0.8mA @ 10 kΩ  nary (depolarizing) phase (usec) 150-250uS  (usec) 400-600uS (uS both phases + 100μS interphase delay)  or Rate (pps) ] 4-125Hz  Symmetrical phases? Yes	Not available	Not available	7.1mA@2kΩ
150-250uS   150-250uS   150-250uS   150-250uS   150-250uS   100ecc)   100uS (uS both phases + 100µS interphase delay)   100 Rate (pps)   4-125Hz   100 Rate (pps)   100 Rate (	Not available	Not available	0.5mA@10kΩ
(usec)	60-350uS	St 049	150uS
Or Rate (pps)   4-125Hz   Symmetrical phases? Yes	700uS (350 uS both phases)	640 µS	400µS
[or Rate (pps)] 4-125Hz Symmetrical phases? Yes			Both phases
Symmetrical phases? Yes	80 to 125 Hz	ZH 001	4 to 99 Hz
	Yes		Yes
waveforms only: Phase duration (include 60-350uS N/A	N/A		100 to 150uS
units) state range, if			

Table 7.3		Neurotech Plus Model 433	Predicate Device Staodyn Max	Predicate Bionicare	Predicate MediTens
			K061516	K971437	K082011
	applicable)(both phases,				
· <u>-</u>	if asyminetrical)				
Net Charge(microcoulombs (uC) per pulse) (if zero,	(uC) per pulse) (if zero,	0μC @ 500Ω	0 μC @ 500 Ω	21 μC @ 500Ω	0 μC @ 500 Ω
state method of achieving zero net charge.)	ro net charge.)	Symmetric, biphasic and leading	Symmetric, biphasic and leading		Symmetric, biphasic and leading
		polarity alternates for each	polarity alternates for each		polarity alternates for each
		successive pulse.	successive pulse.		successive pulse.
Maximum Phase Charge (uC)	(	12.3 μC @ 500 Ω	9 το 21 μC @ 500 Ω	21 μC @ 500Ω	7.5 to 11.25 μC @ 500 Ω
Maximum Current Density (mA/cm <sup>2</sup> , r.m.s)	mA/cm <sup>2</sup> , r.m.s)	0.75mA/cm²(T=1sec)	Program E	0.08 mA/ cm <sup>2</sup>	0.672mA/cm²
$\{$ @ 500 $\Omega$ Where T is the output duration $\}$	utput duration)		Using 2" square electrode = $17.8 \text{ mA/25 cm}^2$ = $0.71 \text{ mA/ cm}^2$	i.e. 8.6mA/108 cm <sup>2</sup> Using 12 x 9 cm electrodes	5cm round electrode)
Maximum Average Current (average absolute value),	(average absolute value),	3.06mA	5.3mA	2.1mA	2.25mA
mA {@ 500 Ω}					
Maximum Average Power Density, (W/ cm2), (using	ensity, (W/ cm2), (using	5.5mW (T=1sec)	6.3 mW/cm²	0.34 mW/cm <sup>2</sup>	4.4mW/ cm²
smallest electrode conductive surface area)	e surface area)		Program E Using 2" square electrode		50mm round electrode
{@ 500 Ω Where T is the output duration}	tput duration}				
Burst Mode (i.e., pulse	(a) Pulses per burst	N/A	8	N/A	N/A
trains):		Burst mode is simply an alternate			Burst mode is simply an alternate
		frequency-pulse witdh combination.			frequency-pulse witdh
		There are actually no intermittent			combination. There are actually
		bursts			no intermittent bursts
	(b) Bursts per second	N/A	2	N/A	N/A
	(c) Burst duration	N/A	60.0	N/A	N/A
	(seconds)				
	(d) Duty Cycle [ Line	N/A	.18	N/A	N/A
	(b) x Line (c) ]				
ON Time (seconds)		N/A	N/A	V/N	N/A
OFF Time (seconds)		N/A	N/A	V/N	N/A
Additional Features (specify, if applicable)	if applicable)	N/A	N/A	N/A	N/A
,					

Table 7.4		Neurotech Plus Model 434	Predicate Device Staodyn Max K061516	Predicate Device MediTens K082011
Mode or Program Name		Plan 4	Program E (Highest output)	Program 3 (99Hz, 150µS)
Waveform (e.g pulsed monophasic, biphasic)	ic, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)	iffied sinusoidal)	Rectangular, with interphase interval	Rectangular	Rectangular, with interphase interval
Maximum Output Voltage (volts)		35.0V @ 500 Ω	30.0V @ 500 Ω	37.5V @ 500 Ω
(+/- 10%)	•	75.0V @ 2 kΩ	Not available	70.0V@ 2 kΩ
		70.3V @ 10 kΩ	Not available	71.8V @ 10 kΩ
Maximum Output Current (specify units)	y units)	70.0mA @ 500 Ω	60.0 mA @ 500 Ω	75.0mA @ 500 \array
(+/- 10%)	•	37.5mA @ 2 kΩ	Not available	35.0mA @ 500 Ω
	•	7.0mA @ 10 kΩ	Not available	7.0mA @ 10 kΩ
RMS Output Voltage (volts)		5.4V @ 500 Ω	8.9V @ 500 Ω	6.5V@500Ω
(%01-/+)	•	11.6V @ 2 kΩ	Not available	14.2V@2kΩ
		6.3V @ 10 kΩ	Not available	4.95V@10kΩ
RMS Output Current (specify units)	(5)	10.8mA @ 500 Ω	17.8mA @ 500 Ω	13mA@500Ω
(%01 -/+)	•	5.8mA @ 2 kΩ	Not available	7.1mA@2kΩ
		0.6mA @ 10 kΩ	Not available	0.5mA@10kΩ
Duration of primary (depolarizing) phase (usec)	t) phase (usec)	120-180uS	90-350uS	150uS
Pulse Duration (usec)		340-460uS (uS both phases + 100µS	700uS (350 uS both phases)	400µS
		interphase delay)		Both phases
Frequency (Hz)  or Rate (pps)		2-80Hz	80 to 125 Hz	4 to 99 Hz
For multiphasic waveforms	Symmetrical phases?	Yes	Yes	Yes
only:	Phase duration	100 to 250μS	60-350uS	100 to 150uS
	(include units) state			
	range, if			
	applicable)(both			
	phases, if			
	asymmetrical)			
Net Charge(microcoulombs (uC) per pulse) (if zero, state	per pulse) (if zero, state	0 μC @ 500 Ω	0μC @ 500Ω	0 μC @ 500 Ω
method of achieving zero net charge.)	rge.)	Symmetric, biphasic and leading polarity	Symmetric, biphasic and	Symmetric, biphasic and leading

Maximum Phase Charge (uC)   10.5μC ® 500 Ω   9 to 21	alternates for each successive pulse. leading polarity alternates for	polarity alternates for each successive
the value), mA  in the value, mA  in the value  in the v	each successive pulse.	pulse.
the value), mA  i.68mA  i.68mA  i.68mA  i.68mA  i.68mA  i.8mA  i.9mW (T=1sec)  is per burst  Burst mode is simply an alternate frequency-pulse witdh combination. There are actually no intermittent bursts  are actually in intermittent bursts  is per second  is per second  is per second  iv Cycle [ Line  iv Cycle	9 to 21 μC @ 500 Ω	7.5 to 11.25 μC @ 500 Ω
ute value), mA  1.68mA  cm²), (using  3.0mW (T=1sec)  s per burst  Burst mode is simply an alternate frequency-pulse witdh combination. There are actually no intermittent bursts  are actually no intermittent bursts  s)  y Cycle [ Line ne (c) ]  N/A  N/A	Usin	0.672mA/cm² 5cm round electrode)
ter value), mA 1.68mA  cm²), (using 3.0mW (T=1sec)  es per burst  Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts  ars actually and intermittent bursts  are actually no intermittent bursts  by Cycle [ Line   N/A   N/A   N/A   N/A   N/A   N/A    N/A   N/A   N/A   N/A   N/A   N/A    N/A   N/A   N/A   N/A   N/A   N/A    N/A   N/A   N/A   N/A   N/A   N/A    N/A   N/A   N/A   N/A   N/A   N/A    N/A   N/A   N/A   N/A   N/A   N/	=17.8 mA/25 cm <sup>2</sup> = 0.71mA/ cm <sup>2</sup>	
cm²), (using 3.0mW (T=1sec)  es per burst  Burst mode is simply an alternate frequency-pulse witdh combination. There are actually no intermittent bursts  arst duration s)  y Cycle [ Line ne (c) ]  N/A  N/A	5.3mA	2.25mA
es per burst  Burst mode is simply an alternate frequency-pulse witch combination. There are actually no intermittent bursts arst duration  s)  V Cycle [ Line ne (c) ]  N/A  N/A		
Es per burst  Burst mode is simply an alternate frequency-pulse witdh combination. There are actually no intermittent bursts arst duration s) y Cycle [ Line ne (c) ]  N/A  N/A		4.4mW/ cm²
(a) Pulses per burst Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts  (b) Bursts per second (c) Burst duration (seconds) (d) Duty Cycle [ Line (b) x Line (c) ]  N/A  N/A	Using 2" sunare electrode	50mm round electrode
(a) Pulses per burst Burst mode is simply an alternate frequency-pulse witch combination. There are actually no intermittent bursts  (b) Bursts per second (c) Burst duration (seconds) (d) Duty Cycle [ Line (b) x Line (c) ]  N/A  N/A		
(b) Bursts per second (c) Burst duration (d) Duty Cycle [ Line (b) x Line (c) ]  (h) M/A	∞	A/N
(b) Bursts per second (c) Burst duration (seconds) (d) Duty Cycle [ Line (b) x Line (c) ]  N/A  frequency-pulse width combination. There are actually no intermittent bursts  (a) Burst duration (b) Duty Cycle [ Line (b) x Line (c) ]  N/A	an alternate	Burst mode is simply an alternate
(b) Bursts per second (c) Burst duration (seconds) (d) Duty Cycle [ Line (b) x Line (c) ]  N/A  N/A	mbination. There	frequency-pulse witch combination.
(b) Bursts per second (c) Burst duration (seconds) (d) Duty Cycle [ Line (b) x Line (c) ]  N/A  N/A	nittent bursts	There are actually no intermittent
(b) Bursts per second (c) Burst duration (seconds) (d) Duty Cycle [ Line (b) x Line (c) ] N/A N/A		bursts
(c) Burst duration (seconds) (d) Duty Cycle [ Line (b) x Line (c) ] N/A N/A	2	
(d) Duty Cycle [ Line (b) x Line (c) ]  N/A  N/A	60'0	
(d) Duty Cycle [ Line (b) x Line (c) ]  N/A  N/A		
(b) x Line (c) 1 N/A N/A N/A	81:	
N/A N/A		
NA	N/A	N/A
	N/A	A/N
Additional Features (specify, if applicable) N/A	N/A	N/A

Table 7.5		Neurotech Plus Model 436	Predicate Device Staodyn Max K061516	Neurotech Plus Model 436	Predicate Device MediStim XP K082011
Mode or Program Name		Plan 3 (TENS)		Plan 4 (NMES)	
Waveform (c.g pulsed monophasic, biphasic)	phasic)	Pulsed, symmetric,	Pulsed, symmetric,	Pulsed, symmetric,	Pulsed, symmetric,
		bíphasic	biphasic	biphasic	biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)	sinusoidal)	Rectangular, with	Rectangular	Rectangular, with	Rectangular, with
		interphase interval		interphase interval	interphase interval
Maximum Output Voltage (volts)(+/- 10%)	10%)	35.0V @ 500 Ω	30.0V @ 500 Ω	35.0V @ 500 Ω	37.5V @ 500 Ω
		75.0V @ 2 kΩ	Not available	75.0V @ 2 kΩ	70.0V@ 2 kΩ
		70.3V @ 10 kΩ	Not available	70.3V @ 10 kΩ	71.8V @ 10 kΩ
Maximum Output Current (specify units)(+/- 10%)	its)(+/- 10%)	70.0mA @ 500 Ω	60.0 mA @ 500 Ω	70.0шА @ 500 Ω	75.0mA @ 500 Ω
		37.5mA @ 2 kΩ	Not available	37.5mA @ 2 kΩ	35.0mA @ 500 Ω
		7.0mA @ 10 kΩ	Not available	7.0 mA @ 10 kΩ	7.0mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)		6.8V @ 500 Ω	Not available	7.7V @ 500 Ω	6.5 V @ 500 Ω
		14.5V @ 2 kΩ	Not available	16,4V @ 2 kΩ	12.1V @ 2 kΩ
		7.8V @ 10 kΩ	Not available	6.3V @ 10 kΩ	7.1V @ 10 kΩ
RMS Output Current (specify units)(+/- 10%)	<i>J</i> - 10%)	13.6mA @ 500Ω	Not available	15.3mA @ 500 Ω	13.0mA @ 500 Ω
		7.3mA @ 2 kΩ	Not available	8.2mA @ 2 kΩ	6.0mA @ 2 kΩ
		0.8mA @ 10 kΩ	Not available	0.6mA @ 10 kΩ	0.7mA @ 10 kΩ
Duration of primary (depolarizing) phase (usec)	ase (usec)	50-250uS	60-350uS	300uS	150-300uS
Pulse Duration (usec)		200-600uS (uS both	700uS (350 uS both	600 uS (100 uS both	400-700us(100 uS both
		phases + 100μS	phases)	phases + 100µS	phases + 100µS
		interphase delay)		interphase delay)	interphase delay)
Frequency (Hz)[ or Rate (pps) ]		4-125Hz	Not available	35-80Hz	2-100Hz
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A	N/A	N/A
	Phase duration (include units) state	N/A	N/A	N/A	N/A
	range, if applicable)(both phases, if				
	asymmetrical)				
Net Charge(microcoulombs (uC) per p	Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving	0 μC @ 500 Ω	0 μC @ 500 Ω	0 μC @ 500 Ω	0 μC @ 500 Ω
zero net charge.)		Symmetric, biphasic and	Symmetric, biphasic and	Symmetric, biphasic and	Symmetric, biphasic and
,		leading polarity alternates	leading polarity alternates	leading polarity alternates	leading polarity alternates

Maximum Phase Charge (uC)  Maximum Current Density (mA/cm², r.m.s)  {@ 500 Ω Where T is the output duration}  Maximum Average Current (average absolute value), mA {@ 500 Ω}  Maximum Average Power Density, (W/ cm²), (using smallest electrode conductive surface area)	Model 436 for each successive pulse. 10.5μC @ 500 Ω 0.69mA/cm²(T=1 sec)	Staodyn Max K061516 for each successive pulse. Not available Not available	Model 436	MediStim XP
Maximum Phase Charge (uC)  Maximum Current Density (mA/cm², r.m.s)  {@ 500 Ω Where T is the output duration}  Maximum Average Current (average absolute value), mA {@ 500 Ω}  Maximum Average Power Density, (W/ cm²), (using smallest electonductive surface area)	for each successive pulse.  10.5μC @ 500 Ω  0.69mA/cm²(T=1 sec)	for each successive pulse.  Not available  Not available		עמסקמון
Maximum Phase Charge (uC)  Maximum Current Density (mA/cm², r.m.s)  (@ 500 Ω Where T is the output duration)  Maximum Average Current (average absolute value), mA {@ 500 Ω}  Maximum Average Power Density, (W/ cm²), (using smallest electonductive surface area)	10.5μC @ 500 Ω 0.69mA/cm²(T=1 sec)	Not available Not available	for each successive pulse.	for each successive pulse.
Maximum Current Density (mA/cm², r.m.s) {@ 500 Ω Where T is the output duration}  Maximum Average Current (average absolute value), mA {@ 500 Ω}  Maximum Average Power Density, (W/ cm²), (using smallest electonductive surface area)	0.69mA/cm²(T=1 sec)	Not available	21.0μC @ 500 Ω	21.0μC @ 500 Ω
(@ 500 \Omega Where T is the output duration)  Maximum Average Current (average absolute value), mA {@ 500 \Omega}  Maximum Average Power Density, (W/ cm²), (using smallest electonductive surface area)			0.78mA/cm²(T=1sec)	mA/cm²(T=1sec)
Maximum Average Current (average absolute value), mA {@ 500 Ω}  Maximum Average Power Density, (W/ cm²), (using smallest electonductive surface area)				
Maximum Average Current (average absolute value), mA {@ 500 Ω}  Maximum Average Power Density, (W/ cm²). (using smallest electonductive surface area)				
Maximum Average Power Density, (W/ cm²), (using smallest electonductive surface area)	2.63mA	Not available	3.36mA	Not available
conductive surface area)	ctrode 4.7mW (T=1sec)	Not available	6.0mW (T=1sec)	Not available
{ @ 500 Ω Where T is the output duration}			٠	
Burst Mode (i.e., pulse trains): (a) Pulses per burst	N/A	V/N	N/A	N/A
(b) Bursts per second	N/A	N/A	N/A	N/A
(c) Burst duration (seconds)	N/A	N/A	N/A	N/A
(d) Duty Cycle [Line (b) x Line (c)	(c) ] N/A	N/A	N/A	N/A
ON Time (seconds)	VIN	N/A	N/A	N/A
OFF Time (seconds)	N/A	N/A	N/A	N/A

		Names to Dive	Developto Denies
Table 7.0		Model 437	MediStim XP K082011
Mode or Program Name	į	Plan 3 (NMES)	
Waveform (c.g pulsed monophasic, biphasic)	iphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)	d sinusoidal)*	Rectangular, with interphase interval	Rectangular, with interphase interval
Maximum Output Voltage (volts)(+/- 10%)	(%01	35.0V @ 500 Ω	37.5V @ 500 Ω
		75.0V @ 2 kΩ	70.0V@ 2 kΩ
		70.3V @ 10 kΩ	71.8V @ 10 kΩ
Maximum Output Current (specify units)(+/- 10%	iits)(+/- 10%)	70.0mA @ 500 $\Omega$	75.0mA @ 500 Ω
		37.5mA @ 2 kΩ	35.0mA @ 500 Ω
		7.0 mA @ 10 kΩ	7.0mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)		5.8V @ 500 Ω	6.5 V @ 500 Ω
		12.4V @ 2 kΩ	12.1V @ 2 kΩ
		5.2V @ 10 kΩ	7.1V @ 10 kΩ
RMS Output Current (specify units)(+/- 10%)	(%01 -/-	11.6mA @ 500 \O	13.0mA @ 500 Ω
		6.2mA @ 2kΩ	6.0mA @ 2 kΩ
		0.5mA @ 10 kΩ	0.7mA @ 10 kΩ
Duration of primary (depolarizing) phase (usec)	ase (usec)	200-270uS	150-300uS
Pulse Duration (usec)		500-640 uS (100 uS both phases + 100µS	400-700us(100 uS both phases + 100μS
		interphase delay)	interphase delay)
Frequency (Hz)[ or Rate (pps) ]		50-60Hz	2-100Hz
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A
	Phase duration (include units) state	N/A	N/N
	range, if applicable)(both phases, if		•
	asymmetrical)		
Net Charge(microcoulombs (uC) per p	Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving	0 μC @ 500 Ω	0μC @ 500Ω
zero net charge.)		Symmetric, biphasic and leading polarity alternates	Symmetric, biphasic and leading polarity
		for each successive pulse.	alternates for each successive pulse.
Maximum Phase Charge (uC)		17.5μC @ 500 Ω	21.0µC @ 500 Ω
Maximum Current Density (mA/cm², r.m.s)	r.m.s)	0.59mA/cm²(T=1 sec)	
{@ 500 $\Omega$ Where T is the output duration}	ation)		

Table 7.6		Neurotech Plus Model 437	Predicate Device MediStim XP K082011
Maximum Average Current (average absolute value), mA { @ 500 Ω}	bsolute value), mA {@ 500 Ω}	1.93mA	Not available
Maximum Average Power Density, (W/ cm conductive surface area) {@ 500 Ω Where T is t	Maximum Average Power Density. (W/ cm²), (using smallest electrode conductive surface area) {@ 500 Ω Where T is the output duration}	3.4mW (T=1 sec)	Not available
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	N/A
	(b) Bursts per second	N/A	N/A
	(c) Burst duration (seconds)	N/A	N/A
	(d) Duty Cycle [ Line (b) x Line (c) ]	N/A	N/A
ON Time (seconds)		N/A	N/A
OFF Time (seconds)		N/A	N/A

Table 7.7		Neurotech Plus Model 438	Predicate Device Staodyn Max K061516
Mode or Program Name		Plan 8	
Waveform (e.g pulsed monophasic, biphasic)	phasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)	sinusoidal)	Rectangular, with interphase interval	Rectangular
Maximum Output Voltage (volts)(+/- 1	10%)	35.0V @ 500 Ω	30.0V @ 500 Ω
		75.0V @ 2 kΩ	Not available
		70.3V @ 10 kΩ	Not available
Maximum Output Current (specify units)(+/- 10%	its)(+/- 10%)	70.0mA @ 500 Ω	60.0 mA @ 500 Ω
		37.5mA @ 2 kΩ	Not available
		7.0mA @ 10 kΩ	Not available
RMS Output Voltage (volts)(+/- 10%)		8.7V @ 500 Ω	Not available
		18.7V @ 2 kΩ	Not available
		7.8V @ 10 kΩ	Not available
RMS Output Current (specify units)(+/-	r-10%)	17.5mA @ 500 Ω	Not available
		9.4mA @ 2 kΩ	Not available
		0.8mA @ 10 kΩ	Not available
Duration of primary (depolarizing) phase (usec)	ase (usec)	50-250uS	60-350uS
Pulse Duration (usec)		200-600uS (uS both phases + 100μS	700uS (350 uS both phases)
		interphase delay)	
Frequency (Hz)[ or Rate (pps) ]		4-125Hz	
For multiphasic waveforms only:	Symmetrical phases?	N/A	N/A
	Phase duration (include units) state	N/A	N/A
	range, if applicable)(both phases, if asymmetrical)		
Net Charge(microcoulombs (uC) per p	Net Charge(microcoulombs (uC) per pulse) (if zero, state method of achieving	0 μC @ 500 Ω	0μC@ 500Ω
zero net charge.)		Symmetric, biphasic and leading polarity	Symmetric, biphasic and leading
		alternates for each successive pulse.	polarity alternates for each successive pulse.
Maximum Phase Charge (uC)		17.5μC @ 500 Ω	
Maximum Current Density (mA/cm2, r.m.s)	r.m.s)	0.89mA/cm²(T=1sec)	

{@ 500 Ω Where T is the output dura	ration}		
Maximum Average Current (average al	absolute value), mA {@ 500 Ω}	4.38mA	
Maximum Average Power Density,	Maximum Average Power Density, (W/ cm²), (using smallest electrode	7.8mW (T=1scc)	
conductive surface area)			
{@ 500 Ω Where T is the output duration}	lon}		
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	N/A
	(b) Bursts per second	N/A	N/A
	(c) Burst duration (seconds)	N/A	N/A
	(d) Duty Cycle [ Line (b) x Line (c) ]	N/A	N/A
ON Time (seconds)		N/A	N/A
OFF Time (seconds)		NA	N/A

Fable /.5		Neurotech Plus	Predicate Device	Prodicate
		Model 439	Staodyn Max K061516	McdiTens K082011
Mode or Program Name		Plan 9 (TENS)	Program E (Highest output)	Program 3
				99Нг, 150µS
Waveform (e.g pulsed monophasic, biphasic)	c, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)	ified sinusoidal)	Rectangular, with interphase	Rectangular	Rectangular, with interphase
		interval		interval
Maximum Output Voltage (volts)		35.0V @ 500 Ω	30.0V @ 500 Ω	37.5V @ 500 Ω
(+/- 10%)		75.0V @ 2 kΩ	Not available	70.0V@ 2 kΩ
		70.3V @ 10 kΩ	Not available	71.8V @ 10 kΩ
Maximum Output Current (specify units	y units	70.0mA @ 500 \array	60.0 mA @ 500 Ω	75.0mA @ 500 Ω
)(+/- 10%)		37.5mA @ 2 kΩ	Not available	35,0mA @ 500 Ω
		7.0mA @ 10 kΩ	Not available	7.0mA @ 10 kΩ
RMS Output Voltage (volts)		6.8V @ 500 Ω	8.9V @ 500 Ω	6.5V@500Ω
(+/- 10%)		14.6V @ 2 kΩ	Not available	14.2V@2kΩ
		7.8V @ 10 kΩ	Not available	4.95V@10kΩ
RMS Output Current (specify units)	(8)	13.6mA @ 500 Ω	17.8mA @ 500 Ω	13mA@500Ω
(+/- 10%)		7.3mA @ 2 kΩ	Not available	7.1mA@2kΩ
		0.8mA @ 10 kΩ	Not available	0.5mA@10kΩ
Duration of primary (depolarizing) phase (usec)	() phase (usec)	150-250uS	60-350uS	150uS
Pulse Duration		400-600uS (uS both phases +	700uS (350 uS both phases)	400μS
(nsec)		100µS interphase delay)		Both phases
Frequency (Hz)[ or Rate (pps) ]		4-125Hz	80 to 125 Hz	4 to 99 Hz
For multiphasic waveforms	Symmetrical Phases?	Yes	Yes	Yes
only:	Phase Duration	100 to 250µS	60-350uS	100 to 150uS
Net Charge(microcoulombs (uC)	Net Charge(microcoulombs (uC) per pulse) (if zero, state method of	θμC @ 500 Ω	0 μC @ 500 Ω	0 μC @ 500 Ω
achieving zero net charge.)		Symmetric, biphasic and	Symmetric, biphasic and leading	Symmetric, biphasic and
		leading polarity alternates for	polarity alternates for each	leading polarity alternates for
		each successive pulse.	successive pulse.	each successive pulse.
Maximum Phase Charge (uC)		10.6μC @ 500 Ω	9 to 21 μC @ 500 Ω	7.5 to 11.25 µC @ 500 Ω

¢ (2 )

Table 7.8		Neurotech Plus Model 439	Predicate Device Staodyn Max K061516	Predicate MediTens K082011
Maximum Current Density (mA/cm <sup>2</sup> , r.m.s) {@ 500 Ω Where T is the output duration}	cm², r.m.s) t duration}	0.70mA/cm <sup>2</sup> (T=1 sec)	Program E Using 2" square electrode =17.8 mA/25 cm <sup>2</sup> = 0.71 mA/ cm <sup>2</sup>	0.672mA/cm² 5cm round electrode)
Maximum Average Current (average absolute value). mA { @ 500 Ω}	age absolute value).	2.66mA	5.3mA	2.25mA
Maximum Average Power Density. (W/ cm²). (using smallest e conductive surface area) {@ 500 \Omega Where T is the output duration}	ity, (W/ cm²), (using smallest electrode Ω Where T is the output duration}	4.7mW (T=1sec)	6.3 mW/cm² Program E Using 2" square electrode	4.4mW/ cm² 50mm round electrode
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A  Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts	   ∞	N/A Burst mode is simply an alternate frequency-pulse width combination. There are actually no intermittent bursts
	(b) Bursts per second		2	
	(c) Burst duration (seconds)		60.0	
	(d) Duty Cycle [Line (b) x Line (c) ]		81.	
ON Time (seconds)		N/A.	N/A	N/A
OFF Time (seconds)		N/A	N/A	N/A
Additional Features (specify, if applicable)	pplicable)	N/A	N/A	N/A

Table 7.9		Neurotech Plus Model 440	Predicate Device Staodyn Max K061516	Predicate MediTens K082011
Mode or Program Name		Plan 9 (TENS)	Program E (Highest output)	Program 3 (99Hz, 150μS)
Waveform (e.g pulsed monophasic, biphasic)	c, biphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)	ified sinusoidal)	Rectangular, with interphase interval	Rectangular	Rectangular, with interphase interval
Maximum Output Voltage (volts)(+/- 10%)	(+/- 10%)	35.0V @ 500 Ω	30.0V @ 500 Ω	37.5V @ 500 Ω
		75.0V @ 2 kΩ	Not available	70.0V@ 2 kΩ
		70.3V @ 10 kΩ	Not available	71.8V @ 10 kΩ
Maximum Output Current (specify units)(+/- 10%)	y units)(+/- 10%)	70.0mA @ 500 Ω	60.0 mA @ 500 Ω	75.0mA @ 500 Ω
		37.5mA @ 2 kΩ	Not available	35.0mA @ 500 Ω
		7.0mA @ 10 kΩ	Not available	7.0mA @ 10 kΩ
RMS Output Voltage (volts)(+/- 10%)	(%0)	6.8V @ 500 Ω	8.9V @ 500 Ω	6.5V@500Ω
		14.6V @ 2 kΩ	Not available	14.2V@2kΩ
		7.8V @ 10 kΩ	Not available	4.95V@10kΩ
RMS Output Current (specify units)(+/- 10%)	1s)(+/- 10%)	13.6mA @ 500 Ω	17.8mA @ 500 Ω	13mA@500Ω
		7.3mA @ 2 kΩ	Not available	7.ImA@2kΩ
		0.8mA @ 10 kΩ	Not available	0.5mA@10kΩ
Duration of primary (depolarizing) phase (usec)	;) phase (usec)	150-250uS	60-350uS	150uS
Pulse Duration (usec)		400-600uS (uS both phases + 100µS	700uS (350 uS both phases)	400μS
		interphase delay)		Both phases
Frequency (Hz)[ or Rate (pps) ]		4-125Hz	80 to 125 Hz	4 to 99 Hz
For multiphasic waveforms	N/A	Yes	Yes	Yes
only:	N/A	100 to 250µS	60-350uS	100 to 150uS
Net Charge(microcoulombs (uC) per pulse)	per pulse)	0μC @ 500Ω	0μC @ 500Ω	θμC @ 500Ω
(if zero, state method of achieving zero net charge.)	g zero net charge.)	Symmetric, biphasic and leading polarity	Symmetric, biphasic and leading	Symmetric, biphasic and leading
		alternates for each successive pulse.	polarity alternates for each successive	polarity alternates for each successive
			pulse.	pulse.
Maximum Phase Charge (uC)		10.6μC @ 500 Ω	9 to 21 μC @ 500 Ω	7.5 το 11.25 μC @ 500 Ω
Maximum Current Density (mA/cm2, r.m.s)	:т² , г.т.s)	0.70mA/cm <sup>2</sup> (T=1scc)	Program E	0.672mA/cm²
{@ 500 Ω Where T is the output duration}	: duration}		Osing 2 square electrode =17.8 mA/25 cm <sup>2</sup>	Scm round electrode)

Table 7.9		Neurotech Plus Model 440	Predicate Device Staodyn Max K061516	Predicate MediTens K082011
			$= 0.71 \text{mA/cm}^2$	
Maximum Average Current (average absolute value), $ mA~\{ @~500~\Omega \} $	rage absolute value),	2.66mA	5.3mA	2.25mA
Maximum Average Power Density, (W) electrode conductive surface area) (@ 500 Ω Where T is the output duration)	Maximum Average Power Density, (W/ cm²), (using smallest electrode conductive surface area)	4.7mW (T=1scc)	6.3 mW/cm <sup>2</sup> <u>Program E</u> Using 2" square electrode	4.4mW/ cm² 50mm round electrode
•	•			
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	V/N	8	NA
		Burst mode is simply an alternate		Burst mode is simply an alternate
		frequency-pulse witch combination.		frequency-pulse witdh combination.
		There are actually no intermittent bursts		There are actually no intermittent bursts
	(b) Bursts per second		2	
	(c) Burst duration (seconds)		0.09	
	(d) Duty Cycle		.18	
	[ Line (b) x Line (c) ]			
ON Time (seconds)		N/A	N/A	N/A
OFF Time (seconds)		N/A	N/A	N/A
Additional Features (specify, if applicable)	pplicable)	N/A	N/A	N/A

Table 7.10		Neurotech Plus Model 441	Predicate Device MediStim XP K082011
Mode or Program Name		Plan 9 (NMES)	
Waveform (e.g pulsed monophasic, biphasic)	iphasic)	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic
Shape (e.g rectangular, spike, rectified sinusoidal)	d sinusoidal)	Rectangular, with interphase interval	Rectangular, with interphase interval
Maximum Output Voltage (volts)		35.0V @ 500 Ω	37.5V @ 500 Ω
(%01 -/+)		75.0V @ 2 kΩ	70.0V@ 2 kΩ
	,	70.3V @ 10 kΩ	71.8V @ 10 kΩ
Maximum Output Current (specify units)	uis)	70.0mA @ 500 Ω	75.0mA @ 500 Ω
(+/- 10%)	<del></del>	37.5mA @ 2 kΩ	35.0mA @ 500 Ω
		7.0 mA @ 10 kΩ	7.0mA @ 10 kΩ
RMS Output Voltage (volts)		8.5V @ 500 Ω	6.5 V @ 500 Ω
(+/- 10%)	,	18.3V @ 2 kΩ	12.1V @ 2 kΩ
		7.0V @ 10 kΩ	7.1V @ 10 kΩ
RMS Output Current (specify units)(+/- 10%)	(%01 -/-	17.1mA @ 500 Ω	13.0mA @ 500 Ω
		9.1mA @ 2 kΩ	6.0mA @ 2 kΩ
	•	0.7mA @ 10 kΩ	0.7mA @ 10 kΩ
Duration of primary (depolarizing) phase (usec)	ase (usec)	300uS	150-300uS
Pulse Duration (usec)	The state of the s	400uS (100 uS both phases + 100μS	400-700us(100 uS both phases + 100μS
		interphase delay)	interphase delay)
Frequency (Hz)[ or Rate (pps) ]		ZH66-01	2-100Hz
For multiphasic waveforms only:	Symmetrical phases?	NA	N/A
	Phase duration (include units) state	N/A	N/A
	range, if applicable)(both phases, if		
	asymmetrical)		
Net Charge(microcoulombs (uC) per pulse) (if	pulse) (if zero, state method of achieving	0 μC @ 500 Ω	0μC @ 500Ω
zero net charge.)		Symmetric, biphasic and leading polarity	Symmetric, biphasic and leading polarity
		alternates for each successive pulse.	alternates for each successive pulse.
Maximum Phase Charge (uC)		21.0μC @ 500 Ω	21.0μC @ 500 Ω

Maximum Current Density (mA/cm², r.m.s) {@ 500 \Q Where T is the output duration}	r.m.s)	0.87mA/cm²(T=1sec)	
Maximum Average Current (average absolute value), mA {@ 500 Ω}	bsolute value), mA {@ 500 Ω}	4.16mA	Not available
Maximum Average Power Density,	Maximum Average Power Density, (W/ cm² ), (using smallest electrode	7.4mW (T=1sec)	Not available
conductive surface area)			
{@ 500 Ω Where T is the output duration	ion)		
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	N/A
	(b) Bursts per second	N/A	N/A
,	(c) Burst duration (seconds)	N/A	N/A
	(d) Duty Cycle [Line (b) x Line (c)]	NA	N/A
ON Time (seconds)		N/A	V/N
OFF Time (seconds)		N/A	V/N

# DEPARTMENT OF HEALTH & HUMAN SERVICES



Food and Drug Administration 10903 New Hampshire Avenue Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

Biomedical Research, LTD c/o Ms. Anne-Marie Keenan Quality & Regulatory Engineer Parkmore Business Park West Galway, Ireland

JAN - 9 2012

Re: K112258

Trade/Device Name: Neurotech Plus, Type 413

Regulation Number: 21 CFR 882.5890

Regulation Name: Transcutaneous electrical nerve stimulator for pain relief

Regulatory Class: II

Product Code: GZJ, NYN, IPF Dated: November 30, 2011 Received: December 5, 2011

## Dear Ms. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <a href="http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm">http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm</a> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a>.

Sincerely yours, Heria Alexander

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices

Office of Device Evaluation Center for Devices and Radiological Health

**Enclosure** 

# **Indications for Use**

510(k) Number (if known):

Device Name: Neurotech Plus, Type 413

Indications for Use: The Neurotech Plus device is indicated for the following:

In combination Neuromuscular Electrical Stimulation (NMES) and Transcutaneous Electrical Nerve Stimulation (TENS) modes, models 431, 432, 433, 434, 436, 439 & 440:

NMES Indications	
Maintain or increase the range of motion	Symptomatic relief and management of chronic, intractable pain
Prevention or retardation of disuse atrophy	Relief of pain associated with arthritis
Re-educate muscles	Adjunctive treatment in the management of post-surgical and post-trauma pain
Relax muscle spasms	Adjunctive therapy in reducing the level of pain and symptoms associated with
Increase local blood circulation	osteoarthritis of the knee (models 431, 432 and 433 only)
Prevention of venous thrombosis of the calf muscles immediately after surgery	

In Neuromuscular Electrical Stimulation (NMES) only mode, models 437 & 441:

NMES Indications	
Maintain or increase the range of motion	
Prevention or retardation of disuse atrophy	1-79-1-20-7-1-20-7-1-20-7-1-20-7-1-20-7-1-20-7-1-20-7-1-20-7-1-20-7-1-20-7-1-20-7-1-20-7-1-20-7-1-20-7-1-20-7-
Re-educate muscles	
Relax muscle spasms	
Increase local blood circulation	
Prevention of venous thrombosis of the calf muscles immediately after surgery	

In Transcutaneous Electrical Nerve Stimulation (TENS) only mode, model 438:

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TENS Indications
Symptomatic relief and management of chronic, intractable pain
Relief of pain associated with arthritis
Adjunctive treatment in the management of post-surgical and post-trauma pain

Prescription Use X Over-The-Counter Use (Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,

Nose and Throat Devices

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